

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MILLENNIUM PHARMACEUTICALS, INC.,)
)
)
Plaintiff,)
)
)
v.) C.A. No. 16-223 (GMS)
)
)
ACTAVIS LLC,)
)
)
Defendant.)

STIPULATION REQUESTING STAY

WHEREAS Plaintiff Millennium Pharmaceuticals, Inc. (“Millennium”) is the holder of New Drug Application No. 21-602 by which the FDA granted approval for VELCADE® for Injection, a proteasome inhibitor, for intravenous or subcutaneous administration for the treatment of patients with multiple myeloma and patients with mantle cell lymphoma;

WHEREAS Defendant Actavis LLC has filed New Drug Application No. 208645 (the “Actavis NDA,” which as used herein shall include NDA No. 208645 as amended, supplemented, or replaced, provided that the product that is the subject of and described in such amended, supplemented, or replaced NDA contains the mannitol ester of bortezomib) for approval to manufacture and sell a generic version of VELCADE® for Injection (the “Actavis NDA Product”) prior to the expiration of U.S. Patent Nos. 6,713,446 (“the ’446 patent”) and 6,958,319 (“the ’319 patent”);

WHEREAS in this action, Millennium filed a Complaint (Dkt. No. 1) in which it asserts that the submission of the Actavis NDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the Actavis NDA Product, before the expiration of the ’446 patent is an act of infringement of at least claims 1-6, 8-10, 39-40, 42, 62, and 63 of the ’446 patent (the “Asserted Claims”) under 35 U.S.C. § 271(e)(2)(A); that the

commercial manufacture, use, offer for sale, sale and/or importation of the Actavis NDA Product would directly infringe at least the Asserted Claims; and that the commercial manufacture, use, offer to sell, sale, or importation of the Actavis NDA Product will contributorily infringe at least the Asserted Claims;

WHEREAS in this action, Actavis filed an Answer and Counterclaims (Dkt. No. 7) in which it denied Millennium's allegations of infringement of the '446 patent; asserted that the claims of the '446 patent are invalid; and counterclaimed for declaratory judgment of non-infringement and invalidity of the '446 patent and '319 patent;

WHEREAS, the expiration of the 30-Month Stay pursuant to 21 U.S.C. 355(j), staying FDA approval of Actavis's NDA, will expire August 22, 2018;

WHEREAS in *Millennium Pharmaceuticals, Inc. v. Sandoz Inc., et al.*, No. 12-1011 (GMS), to which Actavis is a party, the Court has ordered and adjudged that claims 20, 31, 49, and 53 of the '446 patent ("the Sandoz Claims") are invalid due to obviousness ("the Sandoz Judgment");

WHEREAS Millennium disagrees with and has noticed its appeal from the Sandoz Judgment;

WHEREAS the Parties agree that the final outcome of Millennium's appeal from the Sandoz Judgment, including the resolution of any petition for writ of certiorari arising therefrom, may be relevant to the resolution of this action;

WHEREAS the Parties agree that the interests of efficiency may be best served by this action being stayed until the resolution of Millennium's appeal from the Sandoz Judgment, including the resolution of any petition for writ of certiorari arising from the appeal;

WHEREAS the Parties agree that if the final outcome of Millennium's appeal from the Sandoz Judgment, including any petition for writ of certiorari arising therefrom, is that all of the Sandoz Claims are invalid, then Millennium will agree to resolution of this action in Actavis's favor as described in paragraph 3 below;

WHEREAS the Parties agree that if the final outcome of Millennium's appeal from the Sandoz Judgment, including any petition for writ of certiorari arising therefrom, is other than as described in the preceding paragraph, the parties will agree to a case schedule that provides, to the extent reasonably possible, that this action will be ready for trial so as to allow for a resolution of this action sufficiently in advance of the expiration of the 30-Month Stay;

NOW THEREFORE, the parties hereby stipulate and agree as follows, subject to the approval of the Court:

1. Millennium agrees that it will not assert that Actavis infringes the '319 patent based on the Actavis NDA or the Actavis NDA Product;
2. Actavis dismisses with prejudice any claim that the '319 patent is not infringed, invalid, or unenforceable;
3. If the final outcome of Millennium's appeal from the Sandoz Judgment, including any petition for writ of certiorari arising therefrom, is that all of the Sandoz Claims are invalid, then (a) within 30 days of that final outcome the parties will file a stipulation of dismissal with prejudice pursuant to Fed. R. Civ. P. 41(a)(1)(A)(ii); and (b) Millennium will covenant not to sue Actavis or any other party for infringement of the Asserted Claims based on the manufacture, use, sale, offer for sale, and/or importation of the Actavis NDA Product;
4. If the final outcome of Millennium's appeal from the Sandoz Judgment, including any petition for writ of certiorari arising therefrom, is other than as described in paragraph 3, the

parties will meet and confer within 30 days of that final outcome and file a Joint Status Report within 14 days thereafter regarding further proceedings in this action, and will propose a case schedule that ensures, to the extent reasonably possible, that this action will be ready for trial in such time so as to allow for resolution of this action sufficiently in advance of the expiration of the 30-Month Stay; and

5. This case is stayed pending further proceedings in relation to the final outcome of Millennium's appeal from the Sandoz Judgment, including any petition for writ of certiorari arising therefrom, as described in paragraphs 3-4 above.

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SO ORDERED this 11 day of October, 2016

UNITED STATES DISTRICT COURT JUDGE